REMARKS

Claims 1-6 and 11-13 stand pending. Claims 7-10 have been withdrawn pursuant to restriction requirement. Claims 1 and 11 have been amended. Support for said amendments may be found generally throughout the specification, and specifically within paragraphs[0008] to [0010] and [0033] to [0034] of the specification. No new matter has been added by virtue of these amendments.

I. Objections to the Drawings

The Examiner has objected to drawing Figures 4 and 7 for poor readability and Figures 5, 6 and 7 for unacceptable margins. Applicant is in the process of preparing formal acceptable drawings in response to the objections and will submit same upon completion.

II. Objection to the Specification

The Examiner has objected to the specification with regard to Figures 2 and 3. Applicant has amended paragraph [0006] of the specification to refer to Figures 2A and 2B of Figure 2 as well as Figures 3A and 3B of Figure 3. No new matter has been added by virtue of this amendment.

Accordingly, Applicant respectfully posits that this amendment obviates the rejection and respectfully therefore requests that said objection be withdrawn.

III. Objections to the Claims

Claims 1, 6 and 11 are objected to for informalities. Claim 1 has been amended to claim the isomer in singular form, whereas Claims 6 and 11 have been amended to address the typographical/grammatical errors. Accordingly, Applicant respectfully posits that said amendments obviate these objections and that said objections be withdrawn.

IV. Claim Rejections

A. 35 U.S.C. 112, first paragraph

Claims 11-13 stand rejected by the Examiner under 35 U.S.C. 112, first paragraph for lack of enablement. Specifically the Examiner contends that the pharmaceutical compositions of Claims 11-13 are enabling for treatment of hepatitis C (HCV) disease/infection, but not for other viral or immunomodulatory diseases. Applicants respectfully traverse.

Applicants have amended Claim 11 to claim a pharmaceutical composition comprising a pharmacologically effective amount of a positional isomer of pegylated interferon alpha 2a of a specifically recited formula and a therapeutically inert carrier. Applicants therefore respectfully submit that the rejection is obviated. As Claims 12-13 are dependent on Claim 11, Applicants respectfully request that the 112, first paragraph rejection for Claims 11-13 be withdrawn.

B. 35 U.S.C. 112, second paragraph

Claims 11-13 stand rejected by the Examiner under 35 U.S.C. 112, second paragraph for indefiniteness. Specifically the Examiner contends that the claim term "immunomodulatory" is not defined by the specification. Applicants respectfully traverse.

Applicants have amended Claim 11 to claim a pharmaceutical composition comprising a pharmacologically effective amount of a positional isomer of pegylated interferon alpha 2a of a specifically recited formula and a therapeutically inert carrier. Applicants therefore respectfully submit that the rejection is obviated. As Claims 12-13 are dependent on Claim 11, Applicants respectfully request that the 112, second paragraph rejection for Claims 11-13 be withdrawn.

C. 35 U.S.C. 102(b)

1. Claims 1-6 and 11-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bailon et al. Specifically, the Examiner contends that Bailon teaches a 40,000 pegylated moiety of interferon alpha 2a, wherein said pegylated interferon is a mixture of interferon molecules pegylated at lysine 31, lysine 121, lysine 131 and lysine

134, among other lysines, and that said teaching meets the limitation of the present claims. Applicants respectfully traverse.

As noted by the Examiner, Bailon teaches a pegylated interferon alpha 2a which is a mixture of interferon molecules pegylated at various lysine sites, including lysine 31, lysine 121, lysine 131, lysine 70, lysine 83 and lysine 134. (page 198, left column, second paragraph). However, Bailon does not disclose nor teach isolated positional isomers pegylated at lysine 31 or lysine 134. Claim 1 of the present invention is drawn to isolated positional isomers of pegylated interferon alpha 2a, specifically at lysine 31 or lysine 134. Claim 11 of the present invention is drawn to a pharmaceutical composition comprising said isolated positional isomers of pegylated interferon alpha 2a. Accordingly, Applicants respectfully submit that Bailon et al does not anticipate each and every claimed limitation of Claims 1 and 11 (or the claims dependent thereon).

Applicants therefore respectfully request that the 102(b) rejection as to Claims 1-6 and 11-13 be hereby withdrawn and the claims put into condition for allowance.

2. Claims 1-3 and 11-13 also stand rejected under 35 U.S.C. 102(b) as being anticipated by Monkarsh et al. Specifically, the Examiner contends that Monkarsh discloses positional isomers of interferon alpha 2a at various lysine sites, thus anticipating claims 1-3. Applicants respectfully traverse.

Monkarsh discloses pegylated interferon alpha 2a of about 5000 daltons, but does not disclose positional isomers of pegylated interferon alpha 2a wherein the PEG is from about 26000 to 60000 daltons, nor does Monkarsh disclose isolated positional isomers of pegylated interferon alpha 2a wherein the PEG is from about 26000 to 60000 daltons.

However and in contrast, Claim 1 of the present invention is drawn to isolated positional isomers of pegylated interferon alpha 2a, specifically at lysine 31 or lysine 134, wherein the average molecular weight of the polyethylene glycol moiety (PEG moiety) in said pegylated interferon is from 26,000 daltons to 66,000 daltons. Likewise, Claim 11 of the present invention is drawn to a pharmaceutical composition comprising said isolated positional isomers of pegylated interferon alpha 2a, wherein again the

average molecular weight of the polyethylene glycol moiety (PEG moiety) in said pegylated interferon is from 26,000 daltons to 66,000 daltons. Accordingly, Applicants respectfully submit that Monkarsh et al does not anticipate each and every claimed limitation of Claims 1 and 11 (or the claims dependent thereon).

Applicants therefore respectfully request that the 102(b) rejection as to Claims 1-3 and 11-13 be hereby withdrawn and the claims put into condition for allowance.

3. Claims 1-3 and 11-13 also stand rejected under 35 U.S.C. 102(b) as being anticipated by Gilbert et al. (US 5,951,974). Specifically, the Examiner contends that Gilbert discloses a mixture of positional isomers of pegylated interferon with pagination at various lysine sites, including lysine 31, lysine 49, lysine 83, lysine 121, lysine 131 and lysine 134. Applicants respectfully traverse.

Gilbert however discloses only a mixture of interferon polymer isomers, but does not teach isolated positional isomers (See column 6, lines 58ff). In contrast, Claim 1 of the present invention is drawn to isolated positional isomers of pegylated interferon alpha 2a, specifically at lysine 31 or lysine 134, while Claim 11 is drawn to a pharmaceutical composition comprising said isolated positional isomers of pegylated interferon alpha 2a. Accordingly, Applicants respectfully submit that Gilbert et al does not anticipate each and every claimed limitation of Claims 1 and 11 (or the claims dependent thereon).

Applicants therefore respectfully request that the 102(b) rejection as to Claims 1-3 and 11-13 be hereby withdrawn and the claims put into condition for allowance.

D. 35 U.S.C. 102(e)

Claims 1-6 and 11-13 also stand rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al. (US 2004/0136955). Specifically, the Examiner contends that Barker discloses modified interferon polypeptides, including interferon alpha 2a, via pegylation at different lysine sites. Applicants respectfully traverse.

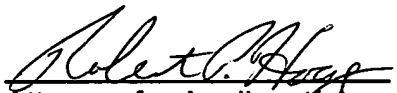
While Barker is asserted to disclose modified interferon polypeptides, including interferon alpha 2a, via pegylation at different lysine sites, including lysines 31, 49, 70,

83, 112, 121, 131, 134 and 164, Barker does not disclose any isolated positional isomers of pegylated interferon. In contrast, Claim 1 of the present invention is drawn to isolated positional isomers of pegylated interferon alpha 2a, specifically at lysine 31 or lysine 134, while Claim 11 is drawn to a pharmaceutical composition comprising said isolated positional isomers of pegylated interferon alpha 2a. Accordingly, Applicants respectfully submit that Barker et al does not anticipate each and every claimed limitation of Claims 1 and 11 (or the claims dependent thereon).

Applicants therefore respectfully request that the 102(e) rejection as to Claims 1-6 and 11-13 be hereby withdrawn and the claims put into condition for allowance.

No further fee is believed to be required in connection with the filing of this Amendment. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,



Attorney for Applicant(s)
Robert P. Hoag
(Reg. No. 39,712)
340 Kingsland Street
Nutley, NJ 07110
Telephone (973) 235-4453
Telefax: (973) 235-2363

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